REMARKS

In the specification, page 12 has been amended to remove a hyperlink, as required by the Examiner.

Claims 1-10 remain in this application. Claims 11-23, and SEQ ID NOS: 1, 3 4, 5, 6, 7 and 8 have been withdrawn as the result of an earlier restriction requirement. Claim 24 is newly added.

In view of the examiner's earlier restriction requirement, applicant retains the right to present claims 11-23, and SEQ ID NOS: 1, 3, 4, 5, 6, 7, and 8 in a divisional application. Claims 5 and 10 have been amended to delete nonelected sequences.

Claim Rejections Under U.S.C. § 112, second paragraph

Claims 1-10 are rejected under U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1, the Examiner indicates sub-claims a), b), c), d), h), i), j), k) and l) lack antecedent basis, are missing steps, and are unclear. In claims 5 and 10, the Examiner states that sub-claims b) and c) do not give specific hybridization conditions and specific function respectively. Also, the Examiner suggests that "gene" be replaced with "a DNA of interest" in claim 6 and all subsequent recitations of this language.

The Examiner has rejected Claim 1(a) on the basis that the recitation "a 5' flanking sequence, a central random sequence, and a 3' flanking sequence" does not give the order of these sequences with respect to one another. The Applicants traverse and respond that the terms "5'", "central", and "3'" are well understood by those of skill in the art and provide an unambiguous description of the order of the sequences with respect to one another. See, for example, Stryer, L., Biochemistry, W.H. Freeman and Company, 1975, at pages 560-561, regarding the 5' to 3'

convention; and King and Stansfield, A Dictionary of Genetics, Oxford University Press, 1985, at page142, regarding the term "flanking."

The Examiner rejects Claim 1(b) on the basis that it "recites a 'preferred plant tissue' but does not [state] what the preference is." The Applicants respectfully state that such generalized description is intentional; note that Claim 2, as originally filed, limited Claim 1 ("wherein said tissue-preferred promoter element is a root-preferred promoter element") and has been amended to provide further differentiation from, and clarification of, Claim 1.

The Examiner further rejects Claim 1(b) on the grounds that "conditions promoting complex formation" is indefinite in that the claim "does not say what the 'complex' is." The Applicants respectfully refer the Examiner to page 13 of the specification, particularly lines 18-20, which provide for "binding the oligonucleotides with proteins from crude nuclear extracts from a plant tissue of interest, separating and isolating the bound complexes on EMSA gels...." See also p. 23, lines 21-24. Applicants point out that "the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification." MPEP 2111.01, citing *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Further, "plain meaning" refers to the meaning given to the term by those of ordinary skill in the art. MPEP 2111.01, citing *In re Sneed*, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983). Applicants respectfully assert that the plain meaning of "complex" as recognized by one of skill in the art may be used to interpret Claim 1(b) and is consistent with use of the term in the specification.

The Examiner further objects to Claim 1(b) on the grounds that "said proteins" lacks antecedent basis. The Applicants respectfully traverse and point out that the term "proteins" appears once within the claim prior to this reference, and thus there can be no ambiguity about the antecedent basis for the term. However, in an effort to expedite prosecution, Claim 1(b) has been amended to recite "said nuclear proteins."

The Examiner has held that an essential step, that of complex formation, is missing in Claim 1. The Applicants thank the Examiner for pointing this out and have amended Claim 1(b) accordingly.

The Examiner has rejected Claim 1(c) on the basis that "said formed complexes" lacks antecedent basis. The Applicants submit that the current amendment to Claim 1(b) obviates this rejection.

The Examiner has rejected Claim 1(d) on the grounds that "said separated complexes" lacks antecedent basis, and for lacking the essential step of producing isolated complexes. The Applicants respectfully traverse and submit that Claim 1(c) as amended, which provides the step of "separating said formed complexes from each other electrophoretically", logically implies that "separated" or "isolated" complexes are produced, and thus provides proper antecedent basis for Claim 1(d).

The Examiner has rejected Claim 1(d) as lacking a step of separating the oligonucleotides from the isolated complexes. Claim 1(d) has been amended to include such step.

The Examiner has rejected Claim 1(h) on the grounds that "assessing" is unclear. The Applicants respectfully direct the Examiner's attention to the specification at page 13, lines 15-30.

The Examiner has rejected Claim 1(i) for the word "increased" lacking comparative basis. Claim 1(i) has been amended.

The Examiner has rejected Claim 1 for a missing step between (j) and (k), that of expressing the expression cassette. Claim 1(k) has been amended to include such step.

The Examiner has rejected Claim 1 for a missing step between (k) and (l), that of choosing an oligonucleotide. Claim 1(l) has been amended to include such step.

The Examiner has rejected Claim 1 as incomplete because the desired product, a tissue-preferred plant promoter element, is not produced by final step of the claim. Claim 1(l) has been amended accordingly.

The Examiner has rejected Claim 5 and Claim 10 for reciting a sequence that hybridizes "under stringent conditions" but not providing specifics of those conditions. The Applicants respectfully direct the Examiner's attention to the specification, pages 10 and 11, wherein "stringent conditions" are defined in detail. However, in an effort to expedite prosecution, and consistent with the support in the specification, Claims 5 and 10 have been amended to comprise specific conditions.

The Examiner has rejected Claim 5 and Claim 10 for reciting "maintain function" but no specific function has been recited. The Applicants respectfully respond that the term "root-preferred plant promoter element" implies, to one of skill in the art, a function; further, the specification describes the function, e.g. at page 3, line 32, through page 4, line 2. However, in an effort to expedite prosecution, Claims 5 and 10 have been amended to specify the function.

The Examiner has rejected Claim 6 for use of the term "gene", and subsequent recitations. Claims 6 and 7 have been amended to replace the term and obviate the rejection.

Claim Rejections Under 35 U.S.C. §112, first paragraph – Written Description

The Examiner has rejected Claims 1-10 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time of filing, had possession of the claimed invention. The Examiner states that the specification does not disclose what structural features need to be present in the claimed sequences to result in the claimed promoter activity, and that there is no description of the structural features to define the claimed genus of sequences. The Examiner cites *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

The Applicants respond that the "Written Description" Guidelines for Examination, Federal Register 66(4):1104-1111, and Comments and Responses at

pages 1099-1104, (all hereinafter "Guidelines") support a finding that the written description requirement has been met.

Claim 1 is a product-by-process claim; Claims 2-4 are dependent therefrom. Therefore, special consideration is appropriate. The Guidelines state, at page 1110, Footnote 52:

> "For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a product-by-process claim. *See, e.g., Fiers v. Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen.*, 927 F.2d at 1206, 18 USPQ2d at 1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process." (emphasis added)

Example 1 describes use of the process to produce the product; thus, Applicants submit that the written description for Claims 1-4 is "clearly satisfied" and ask that the written description rejection be withdrawn as to Claims 1-4.

As to Claims 5-10, Applicants respectfully traverse and request the Examiner's reconsideration. The Guidelines state:

> "Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill In the art to the conclusion that the applicant was in possession of the claimed species is sufficient." (emphasis added) (Fed. Reg. 66(4):1106)

Claims 5 and 10 have been amended to specify a function and to limit the claims to SEQ ID NO: 2 and specific related sequences, which are identified by physical and/or chemical properties. This combination of elements provides ample

written description for Claims 5-10, and Applicants ask that the written description rejection be withdrawn as to Claims 5-10.

Claim Rejections Under 35 U.S.C. § 112, first paragraph – Enablement

The Examiner has rejected Claims 1-10 under 35 U.S.C. § 112, first paragraph, and asserts that the specification, while enabling for claims to a nucleic acid of SEQ ID NO: 2, "does not reasonably provide enablement for any sequences comprising a plant promoter having at least one tissue-preferred plant promoter element, or for a root-preferred plant promoter element where the nucleotide sequence comprises at least 7 contiguous nucleotides of SEQ ID NO: 2 where the nucleotides maintain function." The Examiner states that "the specification does not indicate what structural or functional properties of SEQ ID NO: [2] would represent a plant promoter having at least one tissue-preferred plant promoter element."

The Applicants respectfully respond that the specification provides ample enablement for the amended claims, which provide detailed method steps (Claim 1) for obtaining said plant promoter elements, further described in the Examples (pages 21-29). Support for the specific hybridization conditions and functional requirements of Claims 5 and 10 is found in the specification, including, for example, pages 13, lines 15-30 (methods for identifying and isolating elements); page 8, line 8, through page 11, line 20 (hybridization conditions); and page 4, lines 14 through page 5, line 12 (transformation and expression).

The Examiner cites Doerks (Trends in Genetics 14(6):248-250, June 1998), Smith et al. (Nature Biotech. 15:1222-1223, Nov. 1997), Brenner (Trends in Genetics 15(4):132-133, April 1999), and Borks (TIG 12(10):425-427, October 1996) to support the position that "sequence homology is not sufficient to predict function of encoded sequences." (emphasis added)

Applicants respond that the application does not propose using sequence homology alone to identify plant promoter elements; instead, it offers a combination of techniques, as illustrated in Examples 1, 2, and 3. Detailed methods are provided

for isolation of the root-preferred promoter elements by ROL/protein complex formation. Transient assays are described in detail and serve to confirm the function of the isolated sequences for their promoter activity *in vivo*.

The Examiner further states that using a promoter isolated from one species of plant would produce unpredictable results when said promoter is used to specify expression of a gene in another species of plant, citing Oommenn et al. (Plant Cell 6:1789-1803, 1994). In response, the Applicants respectfully assert that it would be within the realm of reasonable experimentation for one of skill in the art to test a promoter for efficacy in the chosen species. As provided in MPEP 2164.08(b):

> "The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim non-enabled. The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art." *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984).

The Examiner states that "to require one skilled in the art to make changes by random experimentation without guidance as to how to eliminate inoperable embodiments, other than by trial and error is an invitation to experiment requiring excessive and undue experimentation." ..."since specific motifs and structural features are not described."

Applicants respond that the specification provides that a characteristic motif (ACGGTAAA) was present among a class of selected DNA sequences (see p. 24, lines 1-2, and Figure 1). This provides specific guidance for identifying additional root-preferred promoter elements.

As provided in Engel Industries, Inc. v. Lockformer Co., 946 F.2d 1528, 20 USPQ2d 1300 (Fed. Cir. 1991), "The enablement requirement is met if the description enables <u>any mode of making and using</u> the <u>claimed</u> invention." Applicants respectfully ask the Examiner to reconsider whether the invention <u>as now claimed</u> is enabled by the specification.

Claim Rejections Under U.S.C. § 103

Claims 1-10 are rejected under 35 U.S.C. 103 (a) as being obvious over Bruce et al., US 6,140,080, issued October 31, 2000. The Examiner asserts that the claimed promoter (made by the method of providing a mix of oligonucleotides, contacting with nuclear proteins, isolating complexes and then the complexed oligonucleotide, amplifying the oligonucleotide by PCR, isolating the oligonucleotides, putting the oligonucleotide with a promoter and assaying expression) would have been obvious in view of the referenced method of providing an oligonucleotide library, providing nuclear protein extracts, contacting the oligonucleotides with the nuclear protein extract, isolating separated complexed oligonucleotides, and ligation of the oligonucleotide to a promoter of an expression cassette. In addition, the specific method of making would not impart characteristics on the claimed product that would patentably distinguish the product.

The Applicants notes the Examiner's statement that, for applications filed on or after November 29, 1999, the rejection may be overcome by showing that the subject matter of the reference and of the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

As described in MPEP 706.02(l)(2), the following statement is made by the undersigned to establish common ownership or an obligation to assign to the same person or organization:

STATEMENT CONCERNING COMMON OWNERSHIP

The subject of the present application, 09/766,113, and U.S. Patent 6,140,080, were, at the time the present invention was made, owned by, or subject to an obligation of assignment to, Pioneer Hi-Bred International, Inc.

That statement being sufficient evidence to disqualify U.S. Patent 6,140,080 from being used in a rejection under 35 U.S.C. 103(a) against the claims of the present application, Applicants respectfully request that such rejection be withdrawn.

Double Patenting

Claims 1-10 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 16-19 of U.S. Patent No. 6,140,080. The Examiner states that the species claims of patent 6,140,080 renders the genus claims of the instant application obvious. The Examiner asserts that the claimed promoter (as detailed in claim 1, a-l) would have been obvious in view of the method detailed in Examples 1 and 2, columns 12-13, of U.S. 6,140,080.

In response, the Applicants respectfully submit that the claims of 6,140,080 and the presently amended claims are patentably distinct. In light of the showing of common ownership in accordance with MPEP 706.02(l)(1) and 706.02(l)(2), Applicants respectfully request reconsideration of the double patenting rejection.

CONCLUSION

Please charge applicable fees to Deposit Account No. 16-1852 as shown on the enclosed Fee Transmittal.

Applicants believe that all claims under consideration are in condition for allowance, and such action is respectfully requested.

Respectfully submitted,

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